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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,170	11/10/2000	Raymond P. Warrell	10412-025	4982
7590	11/03/2005		EXAMINER	
Patrick J. Birde, Esq. KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			GIBBS, TERRA C	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No. 09/709,170	Applicant(s) WARRELL ET AL.	
	Examiner Terra C. Gibbs	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-23 and 29-33

Claim(s) withdrawn from consideration: \_\_\_\_\_

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.


#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_

Continuation of 5. Applicant's reply has overcome the following rejection(s): Applicant's reply has over the 35 U.S.C. 112, second paragraph rejection against claims 1 and 19 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner is withdrawing this rejection in view of Applicant's amendment to the claims to remove the language "prevention".

Continuation of 11. does NOT place the application in condition for allowance because: Claims 1-5 and 13-18 will remain rejected under 35 U.S.C. 102(b) as being anticipated by Webb et al. (The Lancet, 1997 Vol. 349:1137-1141). In response to this rejection, Applicants remind the Examiner that the instant claims are drawn to a method of treating cancer in a human comprising administering a bcl-2 antisense in one or more cycles of therapy, each cycle of therapy consisting of 2 to 13 days. Applicants argue that Webb et al. teach only the reduction of bcl-2 levels after one week of administration of a bcl-2 antisense. Applicants contend that a reduction of bcl-2 levels does not indicate that the tumor has responded, and is thus not evidence of the treatment of cancer. Further, Applicants contend that Webb only evaluates the tumor response 4 weeks after bcl-2 antisense administration is completed. Applicant's contentions and arguments have been fully considered, but are not found persuasive because the instant claims are drawn to a method of treating cancer in a human comprising administering a bcl-2 antisense oligonucleotide in one or more cycles of therapy, each cycle of therapy consisting of 2 to 13 days. Webb et al. disclose, at Figure 2, the levels of bcl-2 were measured by flow cytometry in lymph node aspirates of patient 6 during 7 days and 14 days of treatment. In fact, Webb et al. disclose, "Bcl-2 levels are reduced at weeks 1 and 2". It is the Examiner's position that at day 7, patient's 6 cancer was inherently treated since the method disclosed by Webb et al. is fully embraced in the methods recited in the instant claims. e.g. Webb et al. teach administering a bcl-2 antisense for less than 14 days. See MPEP § 2112, which states "[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim, but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. 'There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102.' In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims". While the Examiner agrees that a reduction of bcl-2 levels does not necessarily indicate the treatment of cancer, since the method disclosed by Webb et al., as it relates to patient 6, is embraced within the method as instantly claimed, it is the Examiner's position that the instant method would be inherent to the disclosure and teachings of Webb et al.

Claims 1-23 and 29-33 will remain rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al. (The Lancet, 1997 Vol. 349:1137-1141) in view of Bennett et al. [U.S. Patent No: 6,214,986]. In response to this rejection, Applicants argue that this rejection should be withdrawn in view of the failure of Webb et al. to teach or suggest treatment of cancer as recited in the instant claimed. e.g. with less than a 14-day administration of bcl-2 antisense. Applicants argument has been fully considered but is not found persuasive because, as discussed above, while Webb et al. is silent regarding a method of treating cancer, it is the Examiner's position that at day 7, patient's 6 cancer was inherently treated since the method disclosed by Webb et al., as it relates to patient 6, is fully embraced within the method as instantly claimed.



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